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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,158	04/12/2005	Hee-Sup Shin	7037-70886-01	7490
24197 7590 06/04/2007 KLARQUIST SPARKMAN, LLP 121 SW SALMON STREET SUITE 1600 PORTLAND, OR 97204			EXAMINER CHERNYSHEV, OLGA N	
			ART UNIT	PAPER NUMBER
			1649	
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			06/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/531,158	Applicant(s) SHIN ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claim 3 has been cancelled as requested in the amendment filed on April 24, 2007.

Following the amendment, claims 1, 2, 4-9 and 11 are pending in the instant application.

Claims 5-9 and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 21, 2006.

Claims 1, 2 and 4 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
3. Applicant's arguments filed on April 24, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2 and 4 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record specifically explained in section 3 of Paper mailed on October 24, 2006. The claim(s) contains subject matter which was not

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described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant traverses the rejection on the premises that “[i]t is not relevant whether the mouse used is an art-recognized model for depression. Instead what is relevant is whether the assays used are art recognized assays for depression” and refers to two publications on the subject of using behavioral tests in mice for screening of antidepressant drugs (page 4 of the Response). Applicant submits that the transgenic mice lacking the alpha 1B subunit of the N-type calcium channel were used in behavioral tests as explained in Examples 2.1 and 2.2 and that based on the results of “these *in vivo* experiments, one skilled in the art would conclude that reducing or inhibiting N-type calcium channel activity (e.g. by mimicking the knock-out mice) can reduce depression” (bottom at p. 4). Applicant’s arguments have been fully considered but it unpersuasive that the limited results of behavioral tests performed on mice with altered genotype (lacking a gene encoding lacking the alpha 1B subunit of the N-type calcium channel) can support a conclusion that the missing gene is directly involved in human mental depressive disorder. The publications of Porsolt et al. and Steru et al., cited by Applicant (see abstracts presented with the Response), relate to methods of screening of antidepressants by using behavioral despair test and the tail suspension test in mice. There appears to be no disagreement that these tests are art-recognized behavioral tests to screen for psychotropic drugs. However, in the instant case, the tests were used to study the behavior of the genetically altered mice. The evidence of record is inadequate to support a conclusion that the behavioral tests, which “are accepted behavioral tests in the art that can be used to screen for anti-depressant agents” (middle at p. 4 of the Response), can be also used to establish a specific role of the altered gene or its

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relevance to a specific pathological condition. The Examiner maintains that it would require a substantial amount of undue experimentation for a skilled practitioner to extrapolate the limited results of behavioral tests using knock-out mice to methods of treatment of depression in a subject in view of the lack of support of predictability of such extrapolation in the art or in the instant specification as filed.

At pp. 4-5 of the Response, Applicant submits that post-filing publication of Iga et al., 2006 (see abstract presented with the Response), provides evidence that "the N-type calcium channel activity is involved in depression". This argument has been given full consideration; however, the article mainly describes LIM protein, which is known to interact with N-type calcium channel alpha-1B subunit, as being involved in depression. The text of the publication is absolutely silent with respect to N-type calcium channels being specifically positively associated with depression, so that inhibition of such activity would be beneficial for treatment of depression.

The standard of an enabling disclosure is not the ability to make and test if the invention worked but one of the ability to make and use with a reasonable expectation of success. In the instant case, because the instant specification fails to present any factual evidence or provide solid scientific reasoning to support a conclusion that inhibition of N-type calcium channels leads to treatment of depression, The Examiner maintains that the instant specification is not enabling for the claimed method for treating depression, as currently claimed.

"Patent protection is granted in return for an enabling disclosure..., not for vague intimations of general ideas that may or may not be workable." *Genentech*, 108 F.3d at 1365, 42 USPQ2d at 1005. "Tossing out the mere germ of an idea does not constitute enabling disclosure.

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While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public [skilled in the art] to understand and carry out the invention." *Id.* at 1366, 42 USPQ2d at 1005 (emphasis added).

Thus, for reasons in the previous office action record and reasons above, the instant rejection is maintained.

Conclusion

6. No claim is allowed.

7. This application contains claims 5-9 and 11 drawn to an invention nonelected with traverse in Paper filed on August 21, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

May 29, 2007